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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,970	08/04/2003	Paul Alfred Cimiluca	9153R	5176

27752 7590 03/17/2004

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EXAMINER
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WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/633,970

Applicant(s)

CIMILUCA ET AL.

Examiner

EVERETT WHITE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date March 26, 2003.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## DETAILED ACTION

### ***Double Patenting***

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-59 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of Claims 1-56 of copending Application No. 10/369,039. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

### ***Claim Objections***

3. Claims 30 and 54 are objected to because of the following informalities: Claims 30 and 54 improperly listed the term "phosphoric acid" twice. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al (US Patent No. 6,045,847) in view of Marlett et al (US Patent No. 6,287,609) or Colliopoulos (US Patent No. 5,009,916).

Applicants claim a composition comprising a plurality of polysaccharide particles, wherein the polysaccharide particles comprise a polysaccharide component comprising xylose and arabinose, wherein the ratio of xylose to arabinose is at least about 3:1, by weight; and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns. Additional limitations in the dependent claims include a further limitation of the xylose to arabinose ratio; additional components of the polysaccharide particles selected from the group consisting of galactose, glucose, uronic acid and mixtures thereof; a further limitation of the mean particle size distribution of the polysaccharide particles; the composition further comprising starch and gum; the composition further comprising a plurality of agglomerates, wherein the agglomerates comprise the polysaccharide particles and a dispersing component selected from the group consisting of binders, suspending agents, edible acids, and mixtures thereof; specific mean particle size distribution of the agglomerates; the composition further comprising a component selected from the group

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consisting of lubricating agents, emulsifiers, cellulosic materials, and mixtures thereof; and the composition comprising specific types of binders, edible acids and gums at specific amounts.

The Nakamura et al patent shows that compositions that comprise xylose and arabinose are well known in the art. Nakamura et al discloses a water-soluble hemicellulose, which is a polysaccharide containing xylose and arabinose along with other constituent saccharides that include galactose, fucose, rhamnose and galacturonic acid. Nakamura et al discloses that the water-soluble hemicellulose can be used as a dietary fiber additive for foods, which includes rice. Nakamura et al discloses that the water-soluble hemicellulose may be used alone or in an emulsified state with fat or oil to achieve the function of producing a shorter soaking time and allowing a greater amount of water to permeate the rice, but also sets forth that other quality enhancers or additives may be combined therewith as deemed suitable. Examples of quality enhancers and additives listed in the Nakamura et al patent include guar gum, process starch and other starches. Nakamura et al also teaches that the water-soluble hemicellulose as part of a soaking time-shortening agent for grain preparation may be distributed and sold in emulsified or suspended form with a fat or oil, or in solution form in water, saline or a solution of an organic acid such as acetic acid (see column 4, 2<sup>nd</sup> and 3<sup>rd</sup> paragraphs). The water-soluble hemicellulose composition of the Nakamura et al patent comprising the named constituent saccharides and quality enhancers or additives such as guar gum, starch and acetic acid embraces the instantly claimed composition comprising the named polysaccharide components and binders, suspending agents and edible acids thereof. The composition of the instant claims differ from the composition of the Nakamura et al patent by claiming the xylose and arabinose of the polysaccharide component as having a ratio at least about 3:1, by weight.

The Marlett et al patent discloses psyllium seed husks that can be used as a dietary substance to promote laxation and also as a hypocholesterolemic agent (see abstract). Marlett et al teaches the preparation of fractions obtained from psyllium seed husks that comprised mostly of xylose and arabinose. See column 4, lines 48-53 of the

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Marlett et al patent wherein a fraction B obtained from psyllium seed husks has 50% xylose and arabinose by weight and in a preferred embodiment at least 85% xylose and arabinose by weight. Also see column 5, lines 3-6 wherein Marlett et al discloses the ratio of weights of xylose to arabinose of Fraction B as being between 2.5 and 4.5, and between 3.0 and 4.0 in a preferred embodiment, which covers the xylose to arabinose ratio set forth in the instant claims. Furthermore, see Table 1 of the Marlett et al patent wherein other polysaccharide particles are present in compositions of psyllium seed husk fractions that include galactose, glucose and uronic acids, as set forth in the instant claims.

The composition of the instant claims also differs from the composition of the Nakamura et al patent by claiming that the composition comprises a plurality of agglomerates comprising a polysaccharide component comprising xylose and arabinose. The Colliopoulos patent shows that a psyllium high fiber drink mix made by agglomerating a base comprising at least 5 to 99 weight percent psyllium mucilloid is well known in the art (see column 2, lines 33-39). See column 3, 5<sup>th</sup> full paragraph of the Colliopoulos patent, wherein the high fiber drink composition may be manufactured by coating the dry blended ingredients with a selection of materials that include gums and cellulose derivatives, hydrolyzed starch oligosaccharide, mono or disacchaide, a polyglucose or a polymaltose to form an agglomerate by methods well known to one skilled in the art wherein said agglomerate product may be from 0 to 20 weight percent of the water soluble materials set forth in the Colliopoulos patent. Colliopoulos uses the payllium high fiber drink mix as a dietary aid or to control constipation. The Marlett et al patent, discussed above, establishes that psyllium comprises xylose and arabinose in the claimed ratio of 3:1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polysaccharide comprising xylose and arabinose used in the dietary composition of the Nakamura et al patent with a psyllium seed husk fraction comprising xylose and arabinose at a specific ratio and to agglomerate these ingredients in view of the recognition in the art, as evidenced by the Marlett et al and

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Colliopoulos patents, that use of a dietary composition comprising psyllium as a component is effective as a laxative and hypocholesterolemic agent.

One of ordinary skill in this art would be motivated to combine the teachings of the Nakamura et al, Marlett et al and Colliopoulos patents in a rejection of the claims under 35 U.S.C. 103 since all the patents set forth dietary compositions that comprise xylose and arabinose.

6. Claims 1, 15, 16, 19, 27, 28, 32, 33, 35, 43, 44, 52 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al and Marlett et al as applied to Claims 1-56 above, and further in view of Barbera (US Patent No. 5,425,945).

Applicants claim a composition comprising plurality of polysaccharide particles, wherein the polysaccharide particles comprise polysaccharide component comprising xylose and arabinose, wherein the ratio of xylose to arabinose is at least about 3:1, by weight, and wherein the polysaccharide particles have a mean particle size distribution of from about 0.001 microns to about 150 microns.

The information set forth for the Nakamura et al and Marlett et al patents in the above rejection is incorporated into the current rejection. The instant claims differ from the Nakamura et al and Marlett et al patents by claiming polysaccharide particles having a mean particle size distribution of from about 0.001 microns to about 150 microns. In Example 1, the Barbera patent shows that polysaccharide particles having the instantly claimed particle size are well known in the art. Example 1 discloses a psyllium-containing dry blend having a particle size of 100 mesh screen (e.g., 150 microns). The Marlett et al patent establishes that psyllium husk contains xylose and arabinose components in a xylose to arabinose ratio at least 3:1, by weight.

The Barbera patent also discloses agglomerated psyllium husk containing edible acid, wherein the edible acids include citric acid, ascorbic acid, malic acid, succinic acid, tartaric acid and phosphoric acid (see column 4, 4<sup>th</sup> paragraph). The Barbera patent also set forth the use of maltodextrin as the agglomerating material (see column 6, line 13). Furthermore, see column 6, lines 63-68, wherein the Barbera patent discloses preferred agglomerates of psyllium husk having a particle size less than about 80 mesh

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screen (180 microns) be milled such that essentially all of the agglomerates are smaller than about 40 mesh screen (425 microns), and that from about 10% to about 40% of the agglomerates are smaller than about 120 mesh screen (125 microns).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polysaccharide composition comprising xylose and arabinose used in the dietary composition established by the combination of the Nakamura et al patent and the Marlett et al patent with a psyllium-containing composition in view of the recognition in the art, as evidenced by the Barbera patent, that the psyllium material as part of the composition improves the mixability and dispersibility of the composition in liquids.

One of ordinary skill in this art would be motivated to combine the teachings of the Nakamura et al and Marlett et al patents with the teachings of the Barbera patent in a rejection of the claims under 35 U.S.C. 103 since all the patents set forth dietary compositions that comprise xylose and arabinose components.

### ***Summary***

7. All the Claims are rejected.

### ***Examiner's Telephone Number, Fax Number, and Other Information***

8. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

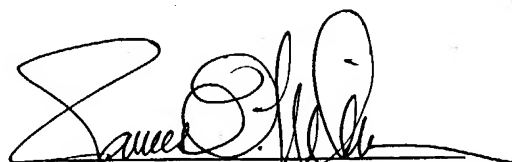


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E. White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600